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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/902,693	Applicant(s) MIHARA ET AL.	
	Examiner Quang Nguyen, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-20 and 22-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 and 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/347,001.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' amendment filed on 8/29/03 has been entered.

Amended claims 17-20, 22-25 and new claims 26-29 are pending in the present application, and they are examined on the merits herein.

New Matter

Amended claims 17-19 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new ground of rejection necessitated by Applicants' amendment.**

Claim 17 recites "wherein the bacterium has a 16S rRNA gene comprising a nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence whose homology is more than 96.5% to the nucleotide sequence of SEQ ID NO:1". Claim 22 recites "wherein the bacterium has a 16S rRNA gene comprising a nucleotide sequence of SEQ ID NO:2 or a nucleotide sequence whose homology is more than 94.0% to the nucleotide sequence of SEQ ID NO:2". 37 CFR 1.118 (a) states that "No amendment shall introduce new matter into the disclosure of an application after the filing date of the application". In the instant case, the limitations that "a nucleotide sequence whose homology is more than 96.5% to the nucleotide sequence of SEQ ID NO:1" and "a nucleotide sequence whose homology is more than 94% to the nucleotide sequence of

SEQ ID NO:2" are considered new matters. There is literal no support in the originally filed specification that Applicants contemplate specifically to utilize a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 96.5% to the nucleotide sequence of SEQ ID NO:1 or a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 94.0% to the nucleotide sequence of SEQ ID NO:2 in the method for producing xylitol or D-xylulose as claimed. While the specification teaches that *Gluconobacter intermedicus* has a 16S rRNA gene that is 96.5% homology to the 16S rRNA gene of the strain P528 (see page 30, lines 1-7) and *Gluconobacter cerinus* has a 16S rRNA gene that is 94% homology to the 16S rRNA gene of the strain S877 (see page 30, lines 7-12), there is no literal written support that Applicants contemplate specifically to make and use a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 96.5% to the nucleotide sequence of SEQ ID NO:1 or a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 94.0% to the nucleotide sequence of SEQ ID NO:2 in the method for producing xylitol or D-xylulose as claimed at the time the application was filed.

Therefore, given the lack of written support in regarding to the aforementioned issue, it would appear that Applicants did not have possession of the claimed invention at the time the application was filed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended claims 17-19 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons set forth immediately above. **This is a new ground of rejection necessitated by Applicants' amendment.**

As enablement requires the specification to teach how to make and use the claimed invention, with the lack of sufficient description and/or guidance provided by the instant specification at the time the application was filed regarding the make and use of a bacterium having a 16S rRNA gene comprising a nucleotide sequence to the nucleotide sequence of SEQ ID NO:1 or a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 94.0% to the nucleotide sequence of SEQ ID NO:2 in the method for producing xylitol or D-xylulose as claimed, it would have required undue experimentation for a skilled artisan to make and use the presently claimed invention.

Written description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New claims 26-29 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new ground of rejection necessitated by Applicants' amendment.**

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d at 1116.

Applicant's invention is drawn to a method for producing xylitol or D-xylulose utilizing a bacterium belongs to the genus *Asaia* whose taxonomic position is at a position of P528 in the molecular phylogenetic tree of Figure 1 or a bacterium belongs to the same genus as the strain P528 having a 16S rRNA gene comprising a nucleotide sequence of SEQ ID NO:1. Applicant's invention is also drawn to a method for producing xylitol or D-xylulose utilizing a bacterium belongs to the genus *Zucharibacter* whose taxonomic position locates at a position of S877 in the molecular phylogenetic tree of Figure 1 or a bacterium belongs to the same genus as the strains S877, S1009, S1019 and S1023 having 16S rRNA genes comprising nucleotide sequences of SEQ ID NOs: 2, 3, 4 and 5, respectively. The specification identifies and characterizes five

microbial strains that have the ability to produce xylitol or D-xylulose from glucose in cell cultures, four of which (S877, S1009, S1019 and S1023 strains) are designated in a new genus *Zucharibacter floricola* and the other (P528 strain) is assigned to a new genus *Asaia ethanolifaciens* by Applicants. The instant claims embraced a method for producing xylitol or D-xylulose using any bacterium as long as it belongs to the same genera as the strains S877, S1009, S1019, S1023 and P528 or the genera *Asaia* and *Zucharibacter* whose taxonomic positions are located at positions of P528 and S877, respectively, in the molecular phylogentic tree of Figure 1. Apart from the functional and generic limitations on the quinone type and GC content of DNA, the instant specification fails to teach common essential core structure(s) or element(s) that are shared between the strains P528, S877, S1009, S1019 and S1023 identified in the instant specification to a broad genus of bacterium to be utilized in the methods as claimed. Nor does the instant disclosure provide a representative number of species of bacterium belong to the genus *Asaia* or the genus *Zucharibacter* with the desired biological activities. The claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art as of Applicants' filing date. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). Since the five isolated microbial strains disclosed in the instant specification represent only a

small portion of the total number of strains in a broad genus encompassed by the instant claims, Applicants have not possessed a representative number of species of strains to describe the broad genus of bacterium that is being utilized in the claimed methods. Particularly, the identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia* having the desired biological activities. The phenotype of one strain from a species of a genus of thousands of bacterial species is not representative of the genus as a whole.

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991). One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Response to Arguments

Applicants' argument related to the above rejection in the Amendment filed on 8/29/03 (page 8) has been fully considered, but it is not found persuasive.

Applicants argue mainly that the bacterium specified in the claimed method is defined by common essential characteristics: the specific sequence of a 16S rRNA gene and the properties of the bacterium, and therefore the bacterium recited in the claims is fully described.

Please note that as written the bacterium specified in new claims 26-29 is not required to possess any specific sequence of a 16S rRNA gene. The bacterium just simply belongs to the genus as the strain P528 or strains S877, S1009, S1019, and S1023.

Claim Rejections - 35 USC § 112

Amended claims 17-20, 22-29 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing xylitol or D-xylulose, which comprises: culturing a bacterium having an ability to produce xylitol or D-xylulose from glucose in a suitable medium to accumulate xylitol or D-xylulose in the medium, and collecting xylitol or D-xylulose from the medium, wherein said bacterium is the isolated microbial strain P528, S877, S1009, S1019 or S1023, does not reasonably provide enablement for a method for producing xylitol or D-xylulose using a bacterium as recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. **This is a new ground of rejection necessitated by Applicants' amendment, and assuming that claims 17-19 and 22-24 have overcome the above New Matter Rejection.**

The specification teaches the isolation and partial characterization of isolated microbial strains P528, S877, S1009, S1019 and S1023. Among the 3000 strains isolated and cultured, the aforementioned strains possess the biochemical characteristics or properties as claimed (e.g., producing xylitol or D-xylulose from

glucose in cell cultures). The specification further teaches that upon analysis of the 16 rRNA nucleotide sequences for the isolated strains P526 and S877, and partial 16 rRNA sequencing analysis for strains S1009, S1019 and S1023, coupled with multiple alignment and evolution distance calculation for the obtained sequences with analogous bacterial sequences available from databases, a molecular phylogenetic tree was established. As a result, the strain P528 was identified as a new species belonging to the genus *Asaia*, and provisionally designated by Applicants as *Asaia ethanolifaciens* sp. nov. The strains S877, S1009, S1019 and S1023 were all identified as microorganisms of a new species belonging to a new genus, and provisionally designated by Applicants as *Zucharibacter floricola* gen. No., sp. nov. The above evidence has been noted and considered. However, the evidence is not reasonably extrapolated to the instant broadly claimed invention for the following reasons.

(1) The breadth of the claims. The instant claims encompass a method for producing xylitol or D-xylulose in culture utilizing any bacterium a long as it belongs to the same genus as the strain P528 or the same genus as the strains S877, S1009, S1019 and S1023, or a bacterium that has a 16S rRNA gene comprising the nucleotide sequence of SEQ ID NO:1 or a nucleotide sequence whose homology is more than 96.5% to SEQ ID NO:1; or a bacterium that has a 16S rRNA gene comprising the nucleotide sequence of SEQ ID NO:2, or a nucleotide sequence whose homology is more than 94.0% to SEQ ID NO:2, along with the biological properties recited in the claims.

(2) The state and the unpredictability of the prior art. At about the effective filing date, species of bacterial strains having the properties required by the methods as claimed are not available or recognized in the prior art. As a result of the present invention, the single strain P528 was identified as a new species belonging to the genus *Asaia*, and provisionally designated by Applicants as *Asaia ethanolifaciens* sp. nov. The strains S877, S1009, S1019 and S1023 were all identified as microorganisms of a new species belonging to a new genus, and provisionally designated by Applicants as *Zucharibacter floricola* gen. No., sp. nov. Additionally, there is no apparent direct relationship that any bacterium containing a 16S rRNA gene having the nucleotide sequence of SEQ ID NO:1, 2, 3, 4, or 5 would possess all the biological properties (e.g., an ability to produce xylitol or D-xylulose from glucose, growth in the presence of 30% glucose, weak or no ability to produce acetic acid from ethanol) required by the methods as claimed, let alone for a bacterium having a 16S rRNA gene comprising a nucleotide sequence whose homology is more than 96.5% to SEQ ID NO:1 or a nucleotide sequence whose homology is more than 94% to SEQ ID NO:2. For example, Suzuki et al. (U.S. Patent 6,340,582) disclose that a microorganism belonging to the genus *Gluconobacter*, including *Gluconobacter oxydans* that has a 16S rRNA gene having 93.9% homology to the 16S rRNA gene of the strain S877 has only been demonstrated to convert D-arabitol (not glucose) to xylitol (see abstract and claims), while the sequence homology of the 16S rRNA genes for the strain P528 and S877 is about 87.7%.

Therefore, it would have required undue experimentation for a skilled artisan to test every single bacterium on a trial-error basis to select the bacterium possessing the recited limitations to be utilized in the methods as claimed.

(3) The amount of direction or guidance provided. Apart from the disclosure of a single isolated bacterial strain P528 newly designated to *Asaia ethanolifaciens* and four closely related bacterial strains S877, S1009, S1019 and S1023 newly designated to *Zucharibacter floricola*, neither the prior arts at the effective filing date of the present application nor the instant specification provide sufficient guidance for a skilled artisan on how to obtain other related bacterial species or related genus having the desired functional characteristics. It is unclear whether the four disclosed microbial strains from *Zucharibacter floricola* represent a broad spectrum of the genus or that they are all clustered at one end of such a genus. The identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia ethanolifaciens* or *Asaia*. The phenotype of one strain from a species of a genus of thousands of bacteria is not representative of the genus as a whole. Moreover, it is unclear whether the soil samples collected from the bank of Tama river or at any other locations or other non-soil samples contain a sufficient number of related bacterial species to represent broad bacterial genera to be utilized in the methods as claimed. Therefore, it would have required undue experimentation for a skilled artisan to practice the full scope of the instant broadly claimed invention, particularly with regard to the amount of experimentation required to screen a large number of bacterial strains representative of

the broad genus of bacterium on a trial-error basis for the practice of the methods as claimed.

With respect to the breadth of the presently claimed invention, Applicants are directed to the decision *In re Shokal*, 113 USPQ 283 (CCPA 1957) wherein is stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

Additionally, the courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel*.).

Accordingly, due to the lack of sufficient guidance provided by the specification on the issues discussed above, the quantity of experimentation necessary, the state of the prior art, and the breadth of the claims, it would have required undue experimentation for one skilled in the art to make and use the instant broadly claimed invention.

Response to Arguments

Applicants' arguments related to the above rejection in the Amendment filed on 8/29/03 (pages 8-9) have been fully considered, but they are not found persuasive.

Applicants argue that the bacterium specified in the claimed method is defined by common essential characteristics: the specific sequence of 16S rRNA and the

properties of the bacterium. In addition, the determination of a 16S rRNA gene sequence of a bacterium and comparing the sequences disclosed in the present application as well as the confirmation that a bacterium has the claimed properties are well within the scope of normal experimentation and undue experimentation for a skilled artisan in the art. Applicants further argue that the five isolated strains in the present invention were obtained from about 3000 strains of osmophilic bacteria, and there is no reasonable expectation that there are no bacteria other than the five strains which have the claimed characteristics.

Applicants' arguments are found to be unpersuasive because as already noted above there is no apparent direct relationship that any bacterium containing a 16S rRNA gene having the nucleotide sequence of SEQ ID NO:1, 2, 3, 4, or 5 would possess all the biological properties (e.g., an ability to produce xylitol or D-xylulose from glucose, growth in the presence of 30% glucose, weak or no ability to produce acetic acid from ethanol) required by the methods as claimed. For example, at about the effective filing date of the present application Suzuki et al. (U.S. Patent 6,340,582) disclose that a microorganism belonging to the genus *Gluconobacter*, including *Gluconobacter oxydans* that has a 16S rRNA gene having 93.9% homology to the 16S rRNA gene of the strain S877 has only been demonstrated to convert D-arabitol (not glucose) to xylitol (see abstract and claims), while the sequence homology of the 16S rRNA genes for the strain P528 and S877 is about 87.7%. Additionally, some of the claims (claims 26-29) do not require the utilization of a bacterium possessing any specific sequence of 16S rRNA in the methods as claimed. Moreover, the physiological art is recognized as

unpredictable (MPEP 2164.03). Therefore, it would have required undue experimentation for a skilled artisan to test every single bacterium on a trial-error basis to select the bacterium possessing the recited limitations to be utilized in the methods as claimed. Furthermore, it is unclear whether the four disclosed microbial strains from *Zucharibacter floricola* would reasonably represent a broad spectrum of the genus or that they are all clustered at one end of such a genus. The identification of a single bacterial strain P528 is not a reasonable representative for the whole genus of *Asaia ethanolifaciens* or *Asaia*. The phenotype of one strain from a species of a genus of thousands of bacteria is not representative of the genus as a whole. The courts have also stated that reasonable correlation must exist between scope of exclusive right to patent application and scope of enablement set forth in the patent application (27 USPQ2d 1662 *Ex parte Maizel*). *In re Shokal*, 113 USPQ 283 (CCPA 1957) stated:

It appears to be well settled that a single species can rarely, if ever, afford sufficient support for a generic claim. *In re Soll*, 25 C.C.P.A. (Patents) 1309, 97 F.2d 623, 38 USPQ 189; *In re Wahlforss et al.*, 28 C.C.P.A. (Patents) 867, 117 F.2d 270, 48 USPQ 397. The decisions do not however fix any definite number of species which will establish completion of a generic invention and it seems evident therefrom that such number will vary, depending on the circumstances of particular cases. Thus, in the case of small genus such as the halogens, consisting of four species, a reduction to practice of three, or perhaps even two, might serve to complete the generic invention, while in the case of a genus comprising hundreds of species, a considerably larger number of reductions to practice would probably be necessary.

Accordingly, amended claims 17-20, 22-29 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth above.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new ground of rejection necessitated by Applicants' amendment.**

In claim 28, it is unclear what is encompassed by the phrase "the bacterium belongs to the same genus as the strain P528 having a 16S rRNA gene comprising a nucleotide sequence of SEQ ID NO:1". Does the bacterium have a 16S rRNA gene comprising a nucleotide sequence of SEQ ID NO:1 or the strain P528 has said 16S rRNA? Or it does not matter as long as the bacterium belongs to the same genus as the strain P528. Clarification is requested because the metes and bounds of the claim are not clearly determined.

Similarly, in claim 29, it is unclear what is encompassed by the phrase "wherein the bacterium belongs to the same genus as the strains S877, S1009, S1019 and S1023 having 16S rRNA genes comprising nucleotide sequences of SEQ ID NOs: 2,3, 4, and 5, respectively". Does the bacterium have a 16S rRNA gene comprising any of the recited nucleotide sequences? Or it does not matter as long as the bacterium belongs to the same genus as the strains S877, S1009, S1019 and S1023. Clarification is requested because the metes and bounds of the claims are not clearly determined.

Conclusion

No claims are allowed.


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (703) 308-1906, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.


GERRY LEFFERS
PRIMARY EXAMINER